

11/5/08

Docket No.: 023189.0101PTUS  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

---

In re Patent Application of:  
Lutz Freitag

Application No.: 10/771,803

Confirmation No.: 3335

Filed: February 4, 2004

Art Unit: 3771

For: TRACHEAL CATHETER AND PROSTHESIS  
AND METHOD OF RESPIRATORY SUPPORT  
OF A PATIENT

---

Examiner: S. O. Douglas

**AMENDMENT AFTER ALLOWANCE**

MS AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INTRODUCTORY COMMENTS**

Under 37 CFR § 1.312, in response to the Notice of Allowance dated October 20, 2008, please amend the above-identified U.S. patent application as follows:

**Amendments to the Drawings** begin on page 2 of this paper and include an attached replacement sheet.

**Amendments to the Claims** begin on page 3 of this paper.

**Remarks/Arguments** begin on page 9 of this paper.

**AMENDMENTS TO THE DRAWINGS**

The attached sheet of drawings replaces Figures 8A and 8B.

Attachment: Replacement sheet

### AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application. Please amend the claims as indicated.

1. (Previously Presented) A method for supplementing respiratory volume of a spontaneously breathing patient, the method comprising:

a) inserting a transtracheal catheter having a first end and a second end into an airway of the patient such that the second end is adapted to terminate in the trachea of the patient, wherein the inserted transtracheal catheter permits spontaneous patient breathing while inserted into the airway of the patient;

b) determining a spontaneous inspiration process and a spontaneous expiration process of the patient; and

c) activating a delivery mechanism based on the determining step to deliver a supplemental gas volume through the transtracheal catheter and into the patient's lungs synchronized with a portion of the patient's spontaneous inspiration process.

2. (Previously Presented) The method of claim 1, wherein the additional amount of supplemental gas volume is administered at an end of the spontaneous inspiration process.

3. (Previously Presented) The method of claim 1, wherein the supplemental gas volume is about between 25 ml – 150 ml.

4. (Previously Presented) The method of claim 2, wherein the supplemental gas volume is about between 25 ml – 150 ml.

5. (Previously Presented) The method of claim 1, further comprising the step of applying a countercurrent of flow into the lung in synchrony with the patient's spontaneous expiration process.

6. (Previously Presented) The method of claim 2, further comprising the step of applying a countercurrent of flow into the lung in synchrony with the patient's spontaneous expiration process.

7. (Previously Presented) An open system ventilation apparatus for supplementing respiration of a spontaneously breathing patient, comprising:

- a) a gas delivery mechanism connected to an oxygen source;
- b) a transtracheal catheter having a first end and a second end, the first end connected to the gas delivery mechanism and the second end adapted and configured for transtracheal insertion into the patient airway without obstructing the patient's spontaneous respiration phases such that the second end terminates in the trachea of the patient;
- c) at least one respiration sensor in communication with the transtracheal catheter and adapted to sense the spontaneous respiration phases of the patient; and
- d) a control unit in communication with the at least one respiration sensor, the control unit adapted and configured to control the gas delivery mechanism to deliver a supplemental volume of gas to the transtracheal catheter in synchrony with a portion of the patient's spontaneous breathing pattern.

8. (Previously Presented) The apparatus of claim 7, further comprising a tracheal prosthesis having a tubular support body, wherein the support body comprises a connection for attachment of the catheter and wherein the catheter is inserted into the tubular support body, wherein the catheter and prosthesis are designed to not occlude the tracheal airway.

9. (Previously Presented) The apparatus of claim 7, further comprising a tracheal prosthesis, wherein the sensor is associated with the tracheal prosthesis and wherein the sensor is not in line with airflow from the ventilator and not in the gas delivery circuit, and at least a portion of the sensor is in airflow in the trachea to measure spontaneous breathing airflow.

10. (Previously Presented) The apparatus of claim 7, further comprising a tracheal prosthesis having a support body, wherein the at least one sensor is coupled with an inner wall of the support body for generating a reference signal.

11. (Previously Presented) The apparatus of claim 9, wherein the second end of the catheter is located in the support body and is deflected approximately parallel to its longitudinal axis (L) and is provided on the end with a jet nozzle.

12. (Previously Presented) The apparatus of claim 10, wherein the second end of the catheter is located in the support body and is deflected approximately parallel to its longitudinal axis and is provided on the end with a jet nozzle.

13. (Previously Presented) The apparatus of claim 7, wherein the gas delivery mechanism is a piston pump, which delivers gas toward the patient when stroking in both directions.

14. (Previously Presented) The apparatus of claim 7, wherein the at least one sensor comprises at least two sensors.

15. (Previously Presented) The apparatus of claim 7, wherein the catheter has a double-lumen configuration, wherein one lumen is used for delivering the supplemental volume of gas in synchrony with the patient's spontaneous inspiratory phase of breathing and the second lumen is used for delivering the supplemental volume of gas in synchrony with the patient's spontaneous expiratory phase of breathing.

16. (Previously Presented) The apparatus of claim 7, wherein the catheter has a double-lumen configuration.

17. (Previously Presented) The apparatus of claim 7, further comprising an additional respiration sensor.

18. (Previously Presented) The apparatus of claim 7, wherein the at least one respiration sensor is adapted to be disposed on the second end of the catheter for positioning in a trachea.

19. (Previously Presented) A tracheal prosthesis comprising:

a tubular support body having a first end and a second end and a lumen therebetween, wherein the tubular support body is sized and configured to terminate within and along a portion

of the trachea without occluding the tracheal airway while permitting the spontaneous breathing of a patient through the lumen;

a connector on the tubular support body between the first end and the second end, the connector configured to attach to a catheter;

a catheter having a first end and a second end and a lumen therebetween wherein the first end is connected to the connector so that the lumen of the catheter is aligned along the tubular support body lumen and toward the second end of the tubular support body; and

at least one respiration detection sensor coupled to the tubular support body, wherein the at least one respiration detection sensor is in communication with the lumen of the tubular support structure without being in line with the lumen of the catheter.

20. (Previously Presented) The tracheal prosthesis of Claim 19, wherein the at least one sensor is coupled with an inner wall of the support body in the trachea.

21. (Previously Presented) The tracheal prosthesis of claim 19, wherein the connector for the catheter adapts the support body to allow the sensor to be connected to a ventilation control system.

22. (Previously Presented) The tracheal prosthesis of claim 20, wherein the sensor comprises at least two sensors, whereby a compensation of measured value difference between the sensors can be provided.

23. (Currently Amended) A catheter for delivering ventilation to a patient comprising:

an elongate body having a first end, a second end and a lumen therebetween wherein the first end is adapted and configured for connection to an outlet so that gas flowing from the outlet moves through the lumen;

the second end of the elongate body is adapted and configured for insertion transtracheally into a trachea of a patient so that the second end may be inserted into the trachea without occluding the tracheal airway of the patient such that the second end terminates in the trachea of the patient; and

at least one respiratory sensor positioned on the elongate body without being in the path of the gas flow through the lumen.

24. (Previously Presented) The catheter of claim 23, wherein a tip of the second end comprises a jet nozzle.

25. (Previously Presented) The catheter of claim 23, wherein the second end has a curved course.

26. (Previously Presented) The catheter of claims 24, wherein the second end has a curved course.

27. (Previously Presented) A method as in claim 1, further comprising the steps of: wearing the delivery mechanism utilized in the activating step so that the spontaneously breathing patient is mobile.

28. (Previously Presented) An apparatus as in claim 7, wherein the gas delivery mechanism and the control unit are configured to be worn by the spontaneously breathing patient.

29. (Previously Presented) A method of supplementing a patient's spontaneous breathing using a wearable ventilation system, the method comprising:

determining the patient's spontaneous breathing by a respiration sensor which measures intra-tracheal airflow;

delivering a supplemental volume to the patient via a transtracheal catheter having a first end and a second end that does not substantially obstruct the patient's airway and the second end is adapted to terminate in the trachea of the patient wherein the supplemental volume is delivered in synchrony with a portion of the patient's inspiratory and/or expiratory spontaneous breath phase; and

providing mobility to the patient by performing the delivering step with the wearable ventilation system that is configured to be worn by the patient.

30. (Previously Presented) The apparatus of Claim 7, wherein the catheter has a jet nozzle and the cross-section of the jet nozzle is less than the cross-section of the catheter so that a discharge rate of supplied oxygen is increased.

31. (Previously Presented) The apparatus of Claim 7, wherein the sensor is a temperature dependent sensor.

32. (Previously Presented) The apparatus of Claim 7, wherein the sensor comprises two thermistor sensors to compensate for measured value differences.

33. (Previously Presented) The apparatus of Claim 13, further comprising a valve to control exhalation counter flow.

34. (Previously Presented) The apparatus of Claim 13, further comprising at least two valves in communication with the piston pump to control gas flow delivering to the patient and recharging of the pump.

35. (Previously Presented) The apparatus of claim 7, the transtracheal catheter further comprising: a jet nozzle.

36. (Previously Presented) The apparatus of claim 7, wherein the control unit is adapted and configured to control the gas delivery mechanism to deliver the volume of gas to intermittently increase the patient's respiratory volume.

37. (Previously Presented) A tracheal prosthesis according to claim 19, wherein the catheter is a jet catheter.

38. (Previously Presented) A method according to claim 29, wherein the supplemental volume is between 25 ml and 150 ml.

39. (Previously Presented) A method according to claim 29, wherein the portion of the patient's inspiratory and/or expiratory spontaneous breath phase is an end of the inspiratory spontaneous breath phase.



### **REMARKS**

Applicant thanks the Examiner for the telephone interview with Applicant's representative on October 30, 2008. The Examiner and Applicant's representative discussed the Examiner's Amendment that accompanied the Notice of allowance, the Drawings, the priority of the application, and a reference, as set forth herein.

The Examiner approved the hand-drawn Figures 8A and 8B in the Notice of Allowance. The Replacement Sheet submitted herewith sets forth a formal version of each of the Figures 8A and 8B. No new matter has been added to the drawings.

In the Notice of Allowance dated October 20, 2008, the Examiner allowed the claims as amended by an Examiner's Amendment. The claims set forth hereinabove include, in non-marked-up format, the Examiner's Amendments set forth in the Notice of Allowance, with one exception. Specifically, Applicant noted that the Examiner's amendment: "In claim 23, line 15: after 'phases' insert --such that the second end terminates in the trachea of the patient--" contained a typographical error, as the word "phases" does not appear in claim 23. In the October 30, 2008 telephone interview, the Examiner stated that the insertion should be made after the word "patient". In accordance with the Examiner's request in the October 30, 2008 telephone interview, Applicant has inserted --such that the second end terminates in the trachea of the patient-- in claim 23, at line 15 as the claim appeared in Applicant's July 2, 2008 amendment, after "patient". This amendment appears in underlined format.

Reference DE 196 26 924 was cited on a Form SB/08, and a copy of the reference was submitted, with an Information Disclosure Statement ("IDS") on January 20, 2006, and Examiner Teena Mitchell considered the drawings. A copy of WO 98/01176 was also filed with the January 20, 2006 IDS. WO 98/01176 claims priority to DE 196 26 924 and contains an English abstract, which was also considered by Examiner Mitchell. As Applicant's representative discussed with the Examiner in the October 30, 2008 telephone interview, the text translation of DE 196 26 924 was not cited on the January 20, 2006 Form SB/08 signed by Examiner Mitchell, and a copy of the translation does not appear in the Image File Wrapper for the present application.

Applicant is resubmitting previously-submitted reference DE 196 26 924 (*see* January 20, 2006 Form SB/08), along with a translation of the text, and a Form SB/08 citing the

reference, adding "and English Translation", and checking box T<sup>6</sup>. Applicant respectfully requests that the Examiner sign the Form SB/08 submitted herewith.

Finally, Applicant notes with appreciation that, in the October 20, 2008 Notice of Allowance, the Examiner acknowledged the present application's claim for foreign priority under 35 U.S.C. § 119 and acknowledged that a certified copy of the priority document had been received. In accordance with the Examiner's suggestion, Applicant is filing herewith a Request for Corrected Official Filing Receipt, to correct the priority application number to read "GERMANY 103 37 138.9 08/11/2003" in lieu of "GERMANY 20/40963-001 08/11/2003".

In view of the above amendment, Applicant believes the pending application is in condition for allowance. Applicant respectfully requests that the Examiner issue a Supplemental Notice of Allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-2228, from which the undersigned is authorized to draw, under Order No. 023189.0101PTUS.

Dated: October 30, 2008

Respectfully submitted,

By Michele V. Frank.  
Michele V. Frank  
Registration No.: 37,028  
PATTON BOGGS LLP  
8484 Westpark Drive, 9th Floor  
McLean, Virginia 22102  
(703) 744-8000  
(703) 744-8001 (Fax)  
Attorney for Applicant

by Jennifer L. King  
Reg # 46,828

Attachments